

## **II. REMARKS**

The courtesies extended by Examiner Oh and Examiner Hartley during the personal interview of April 5, 2006 with the undersigned are acknowledged with appreciation.

### **A. Status of the Claims**

Claim 49 is currently pending and is being added by virtue of the present amendment. Support for new claim 49 can be found in the original specification as filed, e.g., at page 5, line 10; page 7, lines 23-26; page 11, line 16; page 14, line 20; page 17, lines 1-3; original claim 6; and original claim 17. It is respectfully submitted that no matter has been added by virtue of this amendment.

### **B. Statement of Substance of Interview**

During the interview of April 5, 2006, it was discussed that the present invention is directed, in part, to compositions utilizing a packaging system comprising separate dosage forms of lansoprazole and naproxen, and methods thereof. It was further discussed that Depui et al. is directed to two or more active substances in a fixed unit dosage form (i.e., two drugs in the same dosage form). Applicants further discussed that Depui et al. teach away from the present invention in column 2, lines 36-38, and teach away from its combination with Kallgren and Eek by stating that “administration of two or even more different tablets to the patient is not convenient or satisfactory to achieve the most optimal results.”

As set forth in the Interview Summary, it was discussed that the composition claims would be deleted and that method of treatment claims would be presented for further consideration. The Examiners acknowledged that this action would be allowable as method of treatment claims were already present in the application.

The new method claim incorporates the Examiner's suggestion to include the limitation "consisting essentially of" in order to further distinguish the prior art. In addition to the "consisting essentially of" limitations, the method of treatment claim being presented also contains many narrowing limitations which were not included in the independent composition claims of record. These limitations include:

- (i) specific dosage levels (i.e., 15 mg lansoprazole and 500 mg naproxen)
- (ii) specific amounts of dosage forms (i.e., seven lansoprazole dosage forms and fourteen naproxen dosage forms)
- (iii) specific types of dosage forms (lansoprazole capsules and naproxen tablets)
- (iv) specific administration steps (once daily for lansoprazole and twice daily for naproxen)
- (v) three sets of rupturable substrates.

**C. Rejection under 35 U.S.C. § 103(a)**

In the Office Action, the Examiner maintained the rejection of claim 35 under 35 U.S.C. § 103(a) as being unpatentable over the combination of 6,253,920 B1 to Kallgren (hereinafter "Kallgren"); U.S. Patent No. 6,365,184 to Depui et al. (hereinafter "Depui et al."); and WO 88/02342 to Eek (hereinafter "Eek"). In addition, the Examiner rejected claims 36-44 under 35 U.S.C. § 103(a) as being unpatentable over the combination of Kallgren, Depui et al., and Eek.

As discussed during the Interview, claims 35-44 have been cancelled without prejudice and the Examiner is respectfully requested to withdraw the 35 U.S.C. § 103(a) rejection. Applicants respectfully submit that new 49 is not suggested by the combination of Kallgren, Depui et al., and Eek.

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Reply dated April 17, 2006

Response to Office Action dated November 16, 2005



### III. CONCLUSION

Applicants respectfully submit that this application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at the telephone number provided below if he believes that a telephonic interview will advance the prosecution of this application.

Respectfully Submitted,

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